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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,068	01/22/2004	Rene Hen	67780/JPW/AJM/NS	7999

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EXAMINER	
KOLKER, DANIEL E	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,068	HEN ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,28,35,42,48,55 and 62-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, 28, 35, 42, 48, 55, 62-66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant has cancelled claims 2 – 27, 29 – 34, 36 – 41, 43 – 47, 49 – 54, and 56 – 61 in the preliminary amendment filed 22 January 2004. Original claims 1, 28, 35, 42, 48, 55, and 62 – 66 are subject to the election/restriction requirements detailed herein.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to a method for determining whether an agent increases brain progenitor cell division, classified in class 424, subclass 9.1.

II. Claims 28 and 35, drawn to methods of treating or inhibiting diseases by administering agents that can increase brain progenitor cell division, classification dependent upon structure.

III. Claims 42, 48, and 55, drawn to a composition and articles of manufacture, classification dependent upon structure.

IV. Claims 62 and 63, drawn to methods of treating or inhibiting diseases by administering a compound, classified in class 514, subclass 183.

V. Claims 64 - 66, drawn to compounds and articles of manufacture, classified in class 514, subclass 183.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventions that are directed to <u>different</u> methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:

Inventions I is not related to either Invention II or IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods require different starting materials and have different method steps and goals. The method of Invention I is drawn to determining whether an agent can increase the rate of proliferation of brain progenitor cells, and is to be practiced on non-human animals. Inventions II and IV are drawn to methods of inhibiting the onset of or treating diseases and can be practiced on people. Furthermore, the methods of Invention II necessarily require the identification of subjects with or susceptible to certain diseases. This is not a

requirement of the methods of Invention I, and would necessitate a separate search and consideration for any of the diseases listed in claims 28 or 35, presenting a burden for the office.

Invention I is not related to either Invention III or V. Invention I is drawn to a method of determining if an agent increases brain progenitor cell division. Inventions III and V are drawn to a composition and articles of manufacture. While said composition and articles could be used in the methods of Invention I, they are not required for the methods of Invention I as any compound could be used therein. For example, chemicals that are known to have either no effect on brain cell division or chemicals that are known to decrease brain cell division can be used in such an assay, but are specifically excluded from the products of Invention III. Therefore, the products of Invention III and V are independent and distinct from the method of Invention I.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the composition and articles of manufacture of Invention III can be used as positive controls in assays of cell division.

Inventions II and IV are unrelated as they require different starting materials. The methods of Invention II can be practiced with any compound that increases brain progenitor cell division, including, for example fibroblast growth factor (FGF). FGF cannot be used in the methods of Invention IV. Therefore the Inventions are distinct and independent. Furthermore, since the methods require different starting materials, they would require separate search and consideration, presenting a burden for the office.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods of Invention II can be practiced with, for example, FGF, which is well-known to increase the rate of cell division.

Inventions III and IV are not related. Invention III is drawn to products and includes polypeptides such as FGF; Invention IV is drawn to methods of treating or inhibiting the onset of disease and requires specific small molecules. The methods of Invention IV cannot be

practiced with polypeptides such as FGF. Therefore the inventions are distinct and independent.

Inventions III and V are not related. The products of Invention III include such polypeptides as FGF, whereas the products of Invention V are small molecules. Since the products of Invention V are small molecules, and the products of Invention III include polypeptides, the searches for the two inventions would not be co-extensive, presenting a burden for the office.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Invention V can be used as positive controls in assays of cell division.

Requirement for Further Restriction Within Groups II and IV

If applicant elects the methods of treating or inhibiting diseases of either Invention II or IV for prosecution, further restriction is required. Applicant must elect from the following list a single disease to which prosecution will be restricted:

a) anxiety

b) depression

c) a *specific* cognitive disorder

d) a *specific* neuro-degenerative disorder

These diseases have different etiologies, mechanisms, and patient populations. The non-patent literature describing them is not co-extensive, so a search for more than one of them would present a burden for the office. **Applicant is advised that this is not a species election.**

Requirement for Election of Species Within Groups IV and V

This application contains claims directed to the following patentably distinct species of the claimed invention: Hh-Ag 1.1, Hh-Ag 1.2, Hh-Ag 1.3, derivatives of Hh-Ag 1.1, Hh-Ag 1.2, or Hh-Ag 1.3.

If either Invention IV or V is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if

no generic claim is finally held to be allowable. Currently, claims 1, 28, 35, 42, 48, and 55 are generic. If a derivative of Hh-Ag 1.1, Hh-Ag 1.2, or Hh-Ag 1.3 is chosen, Applicant must specifically describe the structure. This can be accomplished, for example, by giving values for a, b, and c in the structure on page 21 of the specification.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

A telephone call was made to Naresh Sritharan on 6 December 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eileen B O'Hara

Daniel E. Kolker, Ph.D.

EILEEN B. O'HARA
PATENT EXAMINER